

## Original Research Article

# Prospective observational study evaluating the outcome of a fixed angle plate (proximal humerus internal locking system) in proximal humerus fractures

Kiran Ramachandran, Jackson Mathew\*, Praveen Koraboina, Ponnezhatu Sebastian John

Department of Orthopaedics, Pushpagiri Institute of Medical Sciences, Thiruvalla, Kerala, India

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**\*Correspondence:**

Dr. Jackson Mathew,

E-mail: [jacksonmathew\\_5120@yahoo.com](mailto:jacksonmathew_5120@yahoo.com)

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### ABSTRACT

**Background:** Proximal humerus fractures are common among elderly. The present study assesses the functional outcomes of fixed angle plate (proximal humerus internal locking system (PHILOS)) in fractures of proximal humerus.

**Methods:** 30 participants aged  $\geq 18$  years with proximal humerus fracture (2, 3 and 4 part) who underwent PHILOS fixation were enrolled. Undisplaced, open, severely comminuted, metastatic, and pathological fractures and with associated head injury and neurovascular injuries were excluded. Clinical and radiological evaluation were done pre and post-operatively. Intraarticular extent of fracture geometry was assessed using 3-dimensional computed tomography. Participants were managed preoperatively with analgesics and shoulder immobilizer followed by preanesthetic check-up and routine investigations and surgery was done once participants were stable. Sample size was calculated assuming excellent or satisfactory results in 80% participants 6 months after surgery, relative precision of 20%,  $\alpha$  of 5% and 10% attrition rate. Institutional ethics committee approved the study and written informed consent was obtained from all study participants.

**Results:** Mean age of study participants was 62.9 (14.9) years and were predominantly females (66.6%, n=20). No significant difference between type of fracture and duration of recovery was observed (p=0.4). 30% participants had post-operative complications, stiffness was the most common (13.3%, n=4) complication. 76.6% (n=23) participants had good functional outcomes. Significant correlation between type of fracture and NEER score was observed (p<0.0001).

**Conclusions:** PHILOS is a preferential implant in proximal humerus fractures due to angular stability, particularly in comminuted fractures in younger patients, and osteoporotic fractures in elderly, thus allowing early mobilization and satisfactory final functional outcome.

**Keywords:** PHILOS plate, Proximal humerus fracture, Post-operative complications

### INTRODUCTION

Proximal humerus fractures are the second most common fractures and constitute 4-5% of all fractures and 45% of all humeral fractures.<sup>1</sup> These fractures constitute 76% of all humeral fractures in individuals over 40 years and are

the 3<sup>rd</sup> most common in elderly after hip and distal end of radius fractures.<sup>2</sup> Dual age distribution has been described for proximal humerus fractures, in healthy young adults and elderly. The occurrence is three times more common in females compared to males.<sup>3</sup> Higher prevalence of these fractures in elderly and in females

following trivial trauma is due to osteoporosis and the etiology of these fractures being common in young adults is high energy trauma. Proximal humeral fractures pose a challenge to orthopaedic surgeons since the recovery depends on bone quality and deforming forces on the fracture site and the bone quality maybe varying due to osteoporosis. 80% of proximal humerus fractures are stable, slightly displaced or non-displaced, and can be managed non operatively followed by early rehabilitation for functional recovery. 20% displaced fractures require surgical management for optimal shoulder function.<sup>4,5</sup> Conventional treatment includes internal fixation with proximal humerus plates, hemiarthroplasty and minimally invasive techniques such as intramedullary nails, screw osteosynthesis and pinning.<sup>6-9</sup> The conventional methods are associated with number of complications such as implant failure (cut out and back out of screws and plate, nail migration), non-union or malunion of the fracture, loss of reduction, impingement syndrome and osteonecrosis of the humeral head.<sup>10-13</sup> The complications following operative management are seen in approximately 50% of the individuals and the incidence increases with age.<sup>14,15</sup> For good functional recovery, anatomical reduction, stable fixation with early mobilization are key factors. Locking plate technology has been developed to overcome shortcomings of conventional treatment options especially in osteoporotic patients and those with metaphyseal comminution. These locking plates work on the principle of the fixed angle between the screws and the locking plate. Locking of screw heads in the plate reduces the possibility of plate pull out and screw toggle thus reducing chances of loss of fracture reduction. Our study was conducted to assess the functional outcome using NEER's shoulder scoring system and the incidence of complications following fixed angle plate (PHILOS) plate fixation for proximal humeral fractures.

## METHODS

30 consecutive participants with proximal humerus fracture admitted in Department of Orthopaedics who underwent PHILOS plate fixation at Pushpagiri Medical College and Research Institute, Thiruvalla between January 2017 to September 2018 were enrolled in our prospective observational study. All participants aged 18 years or older with 2, 3 and 4-part proximal humeral fracture (according to Neer classification), closed fracture of proximal humerus and fit for surgery were enrolled in our study. Participants with undisplaced, open, severely comminuted, metastatic and pathological fractures and fractures with associated head injury and neurovascular injuries were excluded from the study. All participants were evaluated clinically and radiologically (standard and special views) both pre-operatively and post-operatively. Intraarticular extent of fracture geometry was assessed using 3-dimensional computed tomography. Collected data included sociodemographic details, history (mechanism, severity, time since the fracture, associated injuries and functional demand), findings of clinical

examination, complications if any and duration of hospital stay. Fractures were classified according to NEER'S classification and preoperative treatment was with analgesics and shoulder immobilizer. Surgery was performed when the patients were stable after routine investigations and preanesthetic check-up. Institutional Ethics committee approved the study and written informed consent was obtained from all study participants. Sample size was calculated assuming that the participants attaining excellent or satisfactory results to be 80%, 6 months after surgery, relative precision of 20%,  $\alpha$  of 5% and 10% attrition rate. Data was analysed using free software R.

## Procedure

With deltopectoral approach and minimal soft tissue dissection, anatomical relationship of humeral head and greater tuberosity was reduced and fixed temporarily with multiple K-wires. Definitive fixation with locking plate lateral to bicipital groove sparing tendon of long head of biceps 1cm distal to greater tuberosity with screws inserted into head fragment. Proximal locking screws were multidirectional and were inserted unicortically 5-10 mm away from the articular surface through an external guide and were to hold the humeral head and were confirmed with fluoroscopy anteroposterior view in internal and external rotation. Minimum of three bicortically placed distal screws were used. Fluoroscopic images were taken to confirm satisfactory fracture reduction, plate positioning and proper length of screws in the humeral head. Severe comminution or instability was treated by fastening rotator cuff, greater tuberosity, and lesser tuberosity to the plate using non-absorbable sutures. Range of motion of shoulder was checked on the table for impingement. Wound was closed under negative suction, which was removed after 48 hours. Post-operative limb immobilization was with arm pouch with cuff and collar sling. Immediate post-operative X-rays were done to assess the bone alignment and maintenance of reduction. Appropriate antibiotics and analgesics were given. Passive range of motion and pendulum exercises started immediately depending on patient's pain tolerance. In most of the cases suture removal done on post-operative day 10. Patients were discharged with arm pouch and advise to continue pendulum exercises. During first hospital visit arm pouch was removed and started on active assisted external rotation to neutral position movements. All patients were followed up at 6 weeks, 12 weeks, and at 6 months. During each hospital visits, clinical evaluation of wound healing, pain, shoulder range of movements and function were assessed using Neer shoulder scoring system and results were recorded. Fractures were assessed clinically and radiologically for union. Clinically fracture was considered united when there were no complaints of residual pain, sense of insecurity, no bony tenderness at fracture site. Radiologically for union there should not be any fracture line, and three out of four cortices show bridging

trabeculae. Functional assessment was done using Neer’s shoulder scoring system with excellent, satisfactory, unsatisfactory and failure results in scores >89, 80-89, 70-79 and <70 units respectively. Regular wound inspection and dressings done on post-operative days 2<sup>nd</sup>, 5<sup>th</sup> and 10<sup>th</sup> days. Pendulum exercises started on 2<sup>nd</sup> week once pain subsided. Sutures were removed on the 10<sup>th</sup> post-operative day. All patients followed regularly on 6<sup>th</sup> week, 12<sup>th</sup> week and 24<sup>th</sup> week and the following observations are made.

**RESULTS**

Mean age of study participants was 62.9 (14.9) years and were predominantly females (66.6%, n=20). 70% (n=21) had history of fall and 30% (n=9) had history of road traffic accident and 70% (n=21) the right upper limb was affected. 56.6% (n=17) had 3 part fracture, 36.6% (n=11) had 2 part fracture, 3.3% (n=1) had 4 part fracture and fracture dislocation. Gender stratified distribution of fractures are demonstrated in Table 1. Time from injury to surgery was 1.9 (0.6) days and the mean time for surgical procedure was 167.7 (20.2) minutes with no significant difference between the types of fractures. Fracture union took 12 weeks in 73.3% (n=22) and 24 weeks in 26.7% (n=8) participants. The time taken for fracture union among different types of fractures is demonstrated in Table 2.

30% (n=9) participants had post-operative complications of which 55.6% (n=5) had major complications and 44.4% (n=4) had minor complications (Table 3). Post-operative wound infections resolved uneventfully with antibiotics. Osteonecrosis of humeral head and non-union was not observed among our study participants. The mean Neer’s score of the study participants was 82 and was ranged between 64 and 94. The functional outcomes based on Neer’s grading is demonstrated in Table 4. The association between complications and functional outcomes is demonstrated in Table 5. No association was observed between functional outcomes and age.

**Table 1: Gender stratified distribution of fractures.**

Type of fracture	Gender	N (%)
2 part	Male	4 (36.3)
	Female	7 (63.3)
3 part	Male	6 (35.2)
	Female	11 (64.7)
4 part	Male	0
	Female	1 (100)
Fracture dislocation	Male	0
	Female	1 (100)

**Table 2: Frequency table demonstrating fracture union among different types of fractures.**

Type of fracture	Time for union (N)	
	12 weeks	24 weeks
2 part	11	1
3 part	10	6
4 part	0	1
Fracture dislocation	1	0

No significant association was observed between groups (p=0.4).

**Table 3: Complications among study participants.**

Complications	N (%)
Stiffness	4 (13.3)
Impingement	2 (6.7)
Post-operative infection	2 (6.7)
Varus malunion	1 (3.3)

**Table 4: Proportion of participants with various outcomes based on Neer’s grade.**

NEER’s grade	N (%)
Excellent	7 (23.3)
Satisfactory	16 (53.3)
Unsatisfactory	7 (23.3)
Failure	0

**Table 5: Association between complications and functional outcomes.**

Complications	Functional outcome			
	Excellent	Satisfactory	Unsatisfactory	Failure
No	8	12	1	0
Yes	0	3	6	0

Significant association was observed between groups (p=0.002) probably indicating the higher proportion of participants with complications having unsatisfactory outcomes.

**Table 6: Correlation between Neer’s score and type of fracture.**

Type of fracture	N (%)	Mean Neer’s score	Inference
2 part	12 (36.6)	83.6	S
3 part	16 (56.6)	81	S
4 part	1 (3.3)	80.7	S
Fracture dislocation	1 (3.3)	80	S

Significant correlation was observed between type of fracture and Neer’s score (p<0.0001).

## DISCUSSION

Proximal humerus fractures constitute 4-5% of all fractures and the incidence is expected to triple by 2030.<sup>16,17</sup> Management of these fractures remain challenging due to the high proportion of elderly with osteoporosis with this fracture. 15-25% of these fractures are significantly displaced and require internal fixation.<sup>18,19</sup> The outcomes of intervention depend on restoration of anatomical alignment, fractures treated with only rest and early motion will result in functional deficit and associated pain and external support is difficult due to the proximity of the fracture site to the trunk. Untreated displaced fractures have poor outcome due to severe displacement of fragments. The techniques commonly adapted are percutaneous pin fixation, intramedullary nailing, tension band wiring, plate and screw osteosynthesis, and hemiarthroplasty.<sup>7,8,20</sup> Open reduction and internal fixation with non-locking plates and screws has been shown to provide the strongest fixation in non-osteoporotic fractures.<sup>20</sup> Effectiveness of traditional plate-and-screw fixation decreases with bone quality. Three and four-part proximal humerus fractures especially in elderly are associated with high failure rates with plate and screw fixation. Recently plates and screws with angular stability and locking proximal humerus plates for fracture reduction in osteoporotic bone have been developed which provide gentle fracture reduction, reduced avulsion and short immobilization period.<sup>17</sup>

The mean age of study participants were ~63 years and was comparable to other published Indian data and was higher than data from developed countries.<sup>21,22</sup> This could be attributable to the ageing Indian population increasing the proportion of elderly individuals thus increasing the mean age of proximal humeral fractures.<sup>23</sup> 67% of the study participants were females. Proximal humerus fractures has been described as bimodal in presentation, young males and elderly females, possibly due to the high incidence of road traffic accidents and other high impact injuries among young males and due to high incidence of osteoporosis among females making them more susceptible for fractures.<sup>21,24</sup> Right sided fractures were more commonly encountered due to the higher incidence of right hand dominant individuals making the side more vulnerable for fractures due to its use to support during fall.<sup>25</sup> The most common etiology of fracture in our study was fall from height, which has been previously reported as the most common mode of fracture especially in elderly females.<sup>26,27</sup> The commonest types of fractures were 2 part and 3 part fractures which were similar to previous reports.<sup>21,28</sup> The mean time to surgery was ~ 2 days and was lower than some previous studies.<sup>29,30</sup> 2 days for presentation in hospital following history of fall indicates the lower level of awareness regarding fractures following fall among the general public. The mean time for open reduction and internal fixation was ~3 hours and was longer than previous studies which could be due to the higher fracture displacement among participants in our study. No significant difference in duration of surgery

between different fracture types was observed and no association was observed between duration of surgery and the incidence of complications. A proportion of 3-part and all 4-part fractures took 24 weeks for complete union of the fracture segments. This is expected as the time taken for union of fracture is directly proportional to the grade of fracture. 30% participants had complications post operatively and was comparable to the rates of complications from previous reports.<sup>31,32</sup> Among participants with complications, 56% had major complications. Stiffness was the most common complication encountered (13%) followed by impingement (7%) and post-operative infection (7%). These were in contrast to previous studies where avascular necrosis and screw cut out were most common complications.<sup>31,32</sup> Lower rates of non-union and avascular necrosis observed in our study could be due to superior techniques used or due to lack of long term follow up. None of the study participants had failure of procedure and predominant proportion of participants had satisfactory results with surgery. These are good indicators that fixed angle plate (PHILOS) fixation can be done with lower complications than previously described.<sup>31,32</sup> The functional outcomes of our study was comparable with previous studies while the failure rates were lower than these studies.<sup>28,33</sup> Significantly higher proportion of participants who had complications had unsatisfactory functional outcome which is expected. Significant correlation between type of fracture and mean Neer's score was observed ( $p < 0.0001$ ) indicating the higher grade of fractures are associated with lower Neer's scores.

### Limitation

Small sample size and lack of long term follow up were the major limitations of our study.

## CONCLUSION

To conclude, fixed angle plate (PHILOS) is a preferential implant in proximal humerus fractures due to angular stability, particularly in comminuted fractures in younger patients, and osteoporotic fractures in elderly, thus allowing early mobilization and satisfactory final functional outcome.

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